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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/786,322

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EXAMINER

GIBSON, ROY DEAN

ART UNIT

PAPER NUMBER

3739

MAIL DATE

DELIVERY MODE

04/26/2011

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/786,322	<b>Applicant(s)</b> LAFONTAINE, DANIEL M.	
	<b>Examiner</b> Roy D. Gibson	<b>Art Unit</b> 3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 February 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 43,44,46,49,52 and 59-73 is/are pending in the application.
- 4a) Of the above claim(s) 59-63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43,44,46,49,52,64,65 and 69 is/are rejected.
- 7) ☒ Claim(s) 66-68 and 70-73 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

***Entry of Amendment***

Applicant's amendment filed on February 22, 2011 is acknowledged. Claims 43, 44, 46, 49, 52, 59-73 are currently pending. Claims 59-63 have been previously withdrawn as being non-elected without traverse.

***Prior Rejections or Objections***

The following comments pertain to the rejections or objections in the most recent Office action mailed on November 22, 2010. Rejections under 35 U.S.C. 103 are withdrawn, however, new grounds of rejection are presented below. Therefore, this Office action is non-final.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made

Claims 43, 44, 46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al. (7,527,622) in view of Danek et al. (US 2002/0091379). Lane et al. disclose a device for minimally invasive medical treatment in a body of a patient, comprising:

a tubular member (805) having a proximal end and a distal end;

a cryo therapy apparatus (Figure 13) connected to the distal end of the tubular member, wherein the cryo therapy apparatus comprises a first balloon (860) and a second balloon (865), the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails (col. 15, lines 56-67);

wherein the cryo therapy apparatus is sized and arranged for vascular introduction (Abstract).

However, Lane et al. fail to specifically disclose an optical sensor to monitor temperatures created by use of the cryo therapy apparatus, the optical sensor coupled to a retractable member capable of moving independently of the cryo therapy apparatus. But, Danek et al. disclose a catheter with an on-board optical temperature sensor which meets all of the limitations not disclosed by Lane et al. [0037 which reads: examples of temperature detecting elements include thermocouples, infrared optical sensors, etc.] Further, the requirement that the optical sensor is coupled to a retractable member capable of moving independently of the cryo therapy apparatus is considered by the examiner to be merely an obvious engineering design choice well known to one of ordinary skill in the art and that placing of multiple temperature sensors along the interior of the inner balloon would be an obvious alternative equivalent

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because the movement of the optical sensor as claimed would not provide any unexpected results.

Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Lane et al., as taught by Danek et al., to provide an optical sensor, as is well known in the art as an alternative equivalent means of detecting temperature, a quantification device and a separate lumen with an optical fiber as required for monitoring an ice ball formation and temperature.

Claims 52, 64, 65 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lane et al. in view of LePivert (6,551,309). Lane et al. disclose a device for minimally invasive medical treatment in a body of a patient, comprising:

a tubular member having a proximal end and a distal end; a cryo therapy apparatus connected to the distal end of the tubular member and comprising a first balloon and a second balloon, the first and second balloons arranged to define an inner chamber and an outer chamber, at least a portion of the inner chamber being interior of the first balloon and at least a portion of the outer chamber being interior of the second balloon and exterior of the first balloon, a surface of the first balloon configured to retain a coolant within the inner chamber and a surface of the second balloon configured to retain the coolant within the cryo therapy apparatus if the first balloon fails and body of the patient;

wherein the cryo therapy apparatus is sized and arranged for vascular introduction (col. 5, lines 35-67 and col. 8, lines 17-38).

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But, Lane et al. fail to specifically disclose an optical imaging apparatus near the distal end of the tubular member to monitor temperatures resulting from use of the cryo therapy apparatus. However, LePivert discloses an optical imaging apparatus (CIS 17) near the distal end of the tubular member to monitor or detect temperatures resulting from use of the cryo therapy apparatus (col. 4, line 44-col. 5, line 29 and col. 10, lines 34-51). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the device of Lane et al., as taught by LePivert, to provides such an optical imaging device to monitor temperatures resulting from use of the cryo therapy device.

Further to claim 69, Lane et al. provide the temperature sensors (optical imaging apparatus) at least partially within the tubular member (Figure 14, # 875 and # 880 and col. 15, lines 12-67).

### ***Allowable Subject Matter***

Claims 66-68 and 70-73 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on Tu-Th, 7:30 am-4:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Roy D. Gibson/  
Primary Examiner  
Art Unit 3739

April 20, 2011